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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,792	10/24/2003	Phillip E. Gesotti	105.007US01	3594

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EXAMINER	
KAHELIN, MICHAEL WILLIAM	
ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 12/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/693,792	GESOTTI, PHILLIP E.	
	Examiner	Art Unit	
	Michael Kahelin	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-102* is/are pending in the application.

4a) Of the above claim(s) *24-89 and 91-102* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,7-23 and 90* is/are rejected.

7)☒ Claim(s) *4-6* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20040528; 20031024*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of claims 1-23 and 90 in the reply filed on 8/11/2006 is acknowledged. The traversal is on the ground(s) that examination of all claims poses no serious burden on the examiner because examination of all claims requires the same field of search. This is not found persuasive because a serious burden is established, and restriction proper, if the various claimed inventions acquire separate status in the art. This can be shown by a differing classification or art-recognized divergent subject matter. This divergence is illustrated in paragraphs 2-8 of the previous Office Action, and Applicant further concedes that the subject matter is divergent, illustrated by the various proposed classifications in "Remarks" of 8/11/2006. Regardless of Applicant's arguments that Examiner's proposed classifications for the various inventions are incorrect, Applicant does indicate that the various inventions do fall under different classifications, thusly meeting the burden of establishing divergent subject matter. Additionally, the various inventions are drawn to different parts of the body and different diseases, necessitating a different search for each invention, as indicated in the previous Office Action. The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

2. The information disclosure statement filed 10/24/2003 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because two of the references are lacking dates. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-23 and 90 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In regards to claims 1 and 90, the limitation "not synchronized with the patient's gait" is unclear. Examiner has interpreted the operation of the invention to comprise providing stimulation while the patient is walking (i.e. during the patient's gait), per the "plurality" and "timed periodic" limitations. For instance, a cue to take a step with the left leg is given (not during gait), and then a cue to take a step with the right leg is given. It is assumed that this cue to take a step with

the right leg is "during gait" because the left leg has taken a step (i.e. the patient has started walking).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 3, 9-13, 16, 18-21, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Larson et al. (US 4,697,808, hereinafter "Larson").

7. In regards to claims 1 and 3 Larson discloses a method for improving a patient's gait by utilizing the disclosed apparatus and comprises producing a plurality of stimulation prompts at a plurality of points using a plurality of channels placed symmetrically on each leg (Figs. 13 and 14); applying the prompts in a periodic fashion (col. 7, line 41); wherein the prompts are not synchronized with the person's gait (i.e. for standing; col. 5, line 44); each channel is associated with an electrode (Figs. 13 and 14); and a return electrode is inherently activated whenever a stimulation channel is active because a return electrode is required to generate a stimulation voltage. Please note that Examiner is interpreting the "standing" as being "not synchronized with the

patient's gait". Further, Larson discloses that "the body has an inherent time lag of about 100 milliseconds in responding to stimulation", which means that the gait response is not synchronous with stimulation.

8. In regards to claims 9-13, 16, 18, and 19, each of three stimulation channels is associated with a cue clock that activate stimulation electrodes during a cue interval on one leg (col. 7, line 45). Further, three additional channels are activated during the same portion of opposite cue intervals (i.e. 180 degrees out-of-phase; col. 7, line 53).

9. In regards to claims 20, 21, and 23, the pulse width is 300 microseconds, which is approximately 400 microseconds (col. 7, line 52); the pulses are biphasic (col. 7, line 58); and the stimulation current is approximately 10mA (col. 8, line 31).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claim 90 is rejected under 35 U.S.C. 103(a) as being unpatentable over Larson. Larson discloses the essential features of the claimed invention, including ramping the pulse (col. 6, line 11) to account for the human body's response time lag and adjusting the period of the pulse (col. 7, line 8), but does not explicitly disclose that this adjustment is linear. It is well known in the art to adjust variables linearly to reflect the linearity of many natural phenomena, apply a smooth transition between stimulation

values, and minimize computational requirements. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the pulse period as disclosed by Larson in a linear manner to reflect the linearity of many natural phenomena, apply a smooth transition between stimulation values, and minimize computational requirements.

12. Claims 2, 7, 8, 14, 15, 17, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Larson.

13. In regards to claims 2, 7, 8 and 22, Larson discloses the essential features of the claimed invention except for stimulating at a period of 14 milliseconds; stimulating the anterior tibial muscle, gastrocnemius, and rectus femoris; or time division multiplexing stimulation pulses. It is well known in the art to stimulate with a period of 14 milliseconds to ensure patient comfort and avoid cutaneous burning; to stimulate the anterior tibial muscle, gastrocnemius, and rectus femoris to target the main muscles responsible for walking; and to stimulate using time division multiplexing to allow a single processing circuit to apply several signals. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Larson's invention with a pulse period of 14 milliseconds to ensure patient comfort and avoid cutaneous burning; to stimulate the anterior tibial muscle, gastrocnemius, and rectus femoris to target the main muscles responsible for walking; and to stimulate using time division multiplexing to allow a single processing circuit to apply several signals.

14. In regards to claims 14, 15, and 17, Larson discloses the claimed invention but does not disclose expressly the cue intervals of 0.4 seconds and that the third cue clock is active during the second quarter of the first cue interval. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the stimulation parameters as taught by Larson with the claimed stimulation parameters because applicant has not disclosed that the stimulation parameters provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with Larson's stimulation device because both devices have timing intervals that facilitate smooth walking. Therefore, it would have been an obvious matter of design choice to modify Larson's stimulation parameters to obtain the invention as specified in the claims.

Allowable Subject Matter

15. Claims 4-6 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MWK
11/27/06

GEORGE R. EVANISKO
PRIMARY EXAMINER
11/30/06